

REMARKS/ARGUMENTS

The above-identified patent application has been reviewed in light of the Office Action dated January 11, 2008. Claims 1 and 18 have been amended, without intending to abandon or to dedicate to the public any patentable subject matter. No claims have been canceled by this paper. Accordingly, Claims 1-15 and 18 are now pending. As set forth herein, reconsideration and withdrawal of the rejections of the claims are respectfully requested.

Initially, the Applicant would like to thank the Examiner for the courtesies extended during the brief telephone conference that was held on March 21, 2008, between the Examiner and the undersigned. During that telephone conference, the Examiner indicated that certain proposed recitations by the claims would overcome the Gabriel reference. In particular, the Examiner indicated that the claimed feature of a plunger and barrel that retract relative to the inner housing and the outer housing in order to retract the needle into the outer housing overcame the Gabriel reference. The claims as amended above explicitly recite this feature of the invention. Although the Examiner indicated that such features overcame the Gabriel reference, no final agreement regarding allowable subject matter was reached, as the Examiner indicated that an additional search would need to be performed before claims could be finally allowed.

Claims 1-15 and 18 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,544,234 to Gabriel. ("Gabriel"). Claim 9 stands rejected under 35 U.S.C. §103(a) as being obvious over Gabriel. However, all of the claimed elements cannot be found in the Gabriel reference. Accordingly, reconsideration and withdrawal of the rejections of the claims as anticipated by or obvious in view of the Gabriel reference are respectfully requested.

The claimed invention is generally directed to an injection device with a retractable needle. The injection device features an inner housing having a structure that is configured so that the inner housing performs a number of different functions during operation and use of the injection device. As will be explained in detail herein, the Gabriel reference does not teach, suggest or describe an injection device with an inner housing as set forth in the pending claims. Moreover, the Gabriel reference does not teach, suggest or describe an injection device in which the plunger and barrel of a syringe retract relative to the inner housing and the outer housing as claimed.

The Gabriel reference is generally directed to a single use, autoinjector device. In Gabriel, spring 94 initially causes ejection member 92 and displacement member 36 to move

forward together. (Gabriel, col. 4, lines 12-18; Fig. 4.) The action of the displacement member 36 on the flange 20 of the syringe barrel moves the needle 18 forward into the subcutaneous tissue of the patient to a depth determined by the abutment of collar shaped segment 34 against shoulder 54 (Gabriel, Figs. 3-5). The injection is triggered when lug (detent member) 100 is deflected radially inward by projection 70 so that displacement member 36 and ejection member 92 are no longer coupled together. (Gabriel, col. 4, lines 26-49.) At this stage of the injection, further movement of the displacement member 36 is halted, while the ejection member 92 is free to move forward, under the action of the spring 94, so that axial gap 110 closes. (Gabriel, Fig. 5.) The ejection member 92 then moves forward within the displacement member 36, and acts on pressure plate 26 of the syringe 12 to move the piston 22 within the syringe to deliver the injection. (Gabriel, col. 4, lines 43-49, Fig. 5.)

After the entire dose has been delivered from the syringe 12, the injection is complete. As shown in Fig. 5 of Gabriel, the pressure plate 26 of the syringe 12 abuts the ejection member 92, and the displacement member 36 abuts the flange 20 of the syringe. The syringe 12 in Gabriel is therefore prevented from retracting into the interior of the injection device 10. Accordingly, Gabriel does not allow the syringe 12 and the associated needle 18 to retract. Instead, Gabriel provides a needle protection sleeve 46 to cover the needle after an injection. When the needle 18 is pulled out of the subcutaneous tissue, the needle protection sleeve 46 is extended from the housing by its compression spring 56 in order to conceal the needle 18. (Gabriel, Fig. 15.)

Claim 1 is generally directed to an injection device with an outer housing having a number of components located therein. These components include an inner housing intermediate the outer housing and the barrel and plunger (*e.g.* of a syringe). The inner housing is movable by an energy source and operates in three modes. The first mode includes the inner housing moving with the plunger and barrel so that at least part of the needle is moved out of the outer housing. In the second mode, the inner housing acts on and moves with the plunger such that the plunger moves axially into the barrel to expel medicament through the needle. In the third mode, the inner housing acts on neither the plunger nor the barrel. As a result, in this third mode, the plunger and barrel retract relative to the inner housing and the outer housing in order to retract the needle into the outer housing. Moreover, as recited by amended Claim 1, as a result of the plunger and barrel retracting, the needle is retracted such that said at least part of said needle

moved out of the outer housing in the first mode is retracted into the outer housing.

Therefore, as explicitly recited by amended Claim 1, in the third mode the inner housing no longer acts on either the plunger or the barrel and the plunger and barrel retract relative to the inner housing and the outer housing. In addition, the portion of the needle moved out of the outer housing in the first mode is retracted into the outer housing. This is in contrast to the Gabriel reference, in which the components equated by the Office Action with the inner housing remain engaged with syringe components, preventing those components from retracting. Accordingly, the Gabriel device does not allow the syringe to move within the outer housing so as to retract and cover the needle. Instead, Gabriel holds the syringe so that it is axially fixed within the housing and provides a spring loaded sleeve, separate from the outer housing, that extends from the outer housing to cover the needle after the needle is removed from a patient. Therefore, for at least the reason that Gabriel does not teach, suggest or describe an inner housing that in a third mode acts on neither the plunger nor the inner housing so that the plunger and barrel retract to retract the needle into the outer housing, Claim 1 and the Claims dependent therefrom are not unpatentable in view of Gabriel.

In addition, Gabriel does not teach, suggest or describe an inner housing intermediate the outer housing and the barrel and plunger as recited by Claim 1. Instead, the components of Gabriel equated by the Office Action with the recited inner housing do not encompass any part of the barrel of the syringe. Therefore, the Gabriel reference does not meet the recitation of an inner housing intermediate the outer housing and the barrel and plunger as recited by Claim 1. Accordingly, Claim 1 and the claims dependent therefrom should be allowed for at least this additional reason.

Gabriel also does not describe a second mode in which the inner housing is in contact with and acts on the plunger to move the plunger axially but not the barrel so as to expel medicament through the needle. Instead, the displacement member 36 remains engaged with the plunger 20 of the barrel of the syringe at all times. (Gabriel, Figs. 1, 3-5, 15). Accordingly, the rejection of Claim 1 and the claims dependent therefrom are not anticipated by Gabriel for at least this additional reason.

Gabriel also does not teach, suggest or describe a third mode in which the inner housing acts on neither the plunger nor the barrel such that, in use, the plunger and barrel retract relative to the inner housing and the outer housing. As mentioned above, once the patient has pulled the

needle of the Gabriel device out of his tissue, a needle protection sleeve 46 is displaced forward to cover the exposed needle 18. As recited by Claim 1, the plunger and barrel retract relative to the inner housing and in order to retract the needle into the outer housing. In addition, amended Claim 1 specifies that the portion of the needle that is moved out of the outer housing by the axial movement of the plunger and barrel in the first mode is retracted into the outer housing in the third mode. Gabriel does not provide such features. Instead, Gabriel provides a needle protection sleeve 46 that is separate from the housing portion 50. (Gabriel, col. 3, lines 9-15; Fig. 1.) Moreover, the needle protection sleeve 46 of Gabriel is not an outer housing in which components such as an energy source or an inner housing are located, as recited by Claim 1. Therefore, for at least these additional reasons, Claim 1 and the claims dependent therefrom are not anticipated by Gabriel.

In addition, it is noted that at least some of the dependent claims recite additional patentable subject matter. For example, Claim 3 recites that one or more flexible tags included as part of the inner housing are biased radially inwardly into communication with the plunger. It is noted that the flexible detent member of lug 100, which the Office Action has equated with the recited tags, is not biased into communication with the plunger. Therefore, Claim 3 and claims 4 and 5, which depend from Claim 3, should be allowed for at least this additional reason. Moreover, Claim 4 recites that each rear tag is movable out of communication with the plunger when aligned with a corresponding recess in the outer housing. As noted, Gabriel does not provide tags that are biased in communication with a plunger. Accordingly, Gabriel also does not provide tags that move out of communication with the plunger when aligned with a corresponding recess. Therefore, Claims 4 and 5 should be allowed for at least this additional reason. Claim 5 further specifies that each rear tag is substantially T-shaped. There is no disclosure in Gabriel of a T-shaped tag. Accordingly, Claim 5 should be allowed for at least this additional reason.

As an additional example, Claim 10 recites that the injection device includes means for allowing the inner housing to move axially only forward with respect to the outer housing. The Office Action states that Gabriel is fully capable of having such a means, and associates that statement with reference number 112. However, reference number 112 of Gabriel is associated with a proximal end 112 of the ejection member 92, and it is unclear how this structure of Gabriel allows the inner housing to move axially only forward within the outer housing. In

particular, the proximal end 112 of the ejection member 92 is a surface that acts on the pressure plate 26 of the syringe, and would not in any way require movement of the components equated by the Office Action with an inner housing (100, 96, 92) in only one direction within the outer housing. Therefore, Claim should be allowed for at least these additional reasons.

Claim 11 depends from Claim 10, and specifies that the means for allowing the inner housing to move axially only forward is an arrangement of serrations intermediate the inner and outer housings. There is no assertion in the Office Action of where in Gabriel such a feature can be found. Moreover, there in fact appears to be no such disclosure within Gabriel. Accordingly, Claim 11 should be allowed for at least these additional reasons.


Claim 18, as amended, specifies an inner housing with a first portion that engages the barrel and a second portion that moves the plunger. Claim 18 further specifies that the distance between the first and second portions of the inner housing does not change. This is in sharp contrast to Gabriel, in which one component acts on the barrel, a second component acts on the plunger, and in which the portion of the first component that acts on the barrel and the portion of the second component that acts on the plunger come towards one another such that a distance between them decreases while ejecting liquid from the syringe. (Gabriel, Figs. 3, 4, 5.) Independent Claim 18 also recites that the inner housing is intermediate the outer housing and the barrel and plunger. However, the barrel components of Gabriel that the Office Action asserts are equivalent to the inner housing are not intermediate at least the barrel and the outer housing. In particular, those components do not extend around the barrel. In addition, Gabriel does not discuss engaging the barrel with the inner housing and moving the barrel and plunger axially in a first direction by means of the inner housing. Instead, the ejection member of Gabriel acts only on the plunger, and the displacement member acts on the barrel. Moreover, the ejection member of Gabriel does not comprise an inner housing. Similarly, Gabriel does not describe an inner housing that engages the plunger to move the plunger axially in the first direction. The Gabriel reference also does not teach, suggest or describe disengaging the inner housing after causing medicament to be expelled through the needle, and retracting the needle into its biased position wholly inside the outer housing by retracting the plunger and the barrel relative to the inner housing and the outer housing. Therefore, for all of these reasons, the rejection of Claim 18 should be reconsidered and withdrawn.

As discussed herein, the Gabriel reference does not teach, suggest or describe each and

every element set forth in the pending claims. Accordingly, early notification of allowance is respectfully requested. The Examiner is invited to contact the undersigned by telephone if doing so would expedite the resolution of this case.

Respectfully submitted,

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